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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------------------------------------|-------------|----------------------|------------------------------|------------------|
| 10/594,939 | 08/02/2007 | Haruo Sugiyama | 14875-168US1 CI-A0401P-US | 9482 |
| 26161 | 7590 | 10/16/2008 | EXAMINER | |
| FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | GIBBS, TERRA C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1635 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 10/16/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

| | | | |
|------------------------------|--------------------------------------|----------------------------------------|--|
| Office Action Summary | Application No. 10/594,939 | Applicant(s) SUGIYAMA ET AL. | |
| | Examiner TERRA C. GIBBS | Art Unit 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicant's Preliminary Amendment filed September 28, 2006.

Claims 6, 7, and 10-12 have been amended.

Claims 1-20 are pending in the instant application.

Claims 1-20 are subject to restriction as detailed below:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-4, drawn to a cell growth-suppressing agent, comprising a double-stranded RNA (dsRNA), wherein the dsRNA comprises an RNA complementary to a 17AA site of a WT1 gene transcript, and wherein the dsRNA comprises the pair of the nucleotide sequence of SEQ ID NO:1, and the nucleotide sequence of SEQ ID NO:2, classifiable in class 536, subclass 24.5, for example.
- II. Claims 5, 9, 14, 16, 18, and 20, drawn to a cell growth-suppressing agent, comprising a dsRNA, wherein the dsRNA comprises an RNA complementary to WT1 gene transcript, wherein the dsRNA comprises an RNA encoded by the DNA of any one of (a) to (c), and an RNA complementary to said RNA: (a) a DNA comprising the nucleotide sequence of SEQ ID NO:9; (b) a DNA that hybridizes under stringent conditions with a DNA comprising the nucleotide sequence of SEQ ID

- NO:9; and (c) a DNA comprising the nucleotide sequence of SEQ ID NO:11, classifiable in class 536, subclass 24.5, for example.
- III. Claims 5, 9, 14, 16, 18, and 20, drawn to a cell growth-suppressing agent, comprising a dsRNA, wherein the dsRNA comprises an RNA complementary to WT1 gene transcript, wherein the dsRNA comprises an RNA encoded by the DNA of any one of (a) to (c), and an RNA complementary to said RNA: (a) a DNA comprising the nucleotide sequence of SEQ ID NO:12; (b) a DNA that hybridizes under stringent conditions with a DNA comprising the nucleotide sequence of SEQ ID NO:12; and (c) a DNA comprising the nucleotide sequence of SEQ ID NO:13, classifiable in class 536, subclass 24.5, for example.
- IV. Claims 5, 9, 14, 16, 18, and 20, drawn to a cell growth-suppressing agent, comprising a dsRNA, wherein the dsRNA comprises an RNA complementary to WT1 gene transcript, wherein the dsRNA comprises an RNA encoded by the DNA of any one of (a) to (c), and an RNA complementary to said RNA: (a) a DNA comprising the nucleotide sequence of SEQ ID NO:14; (b) a DNA that hybridizes under stringent conditions with a DNA comprising the nucleotide sequence of SEQ ID NO:14; and (c) a DNA comprising the nucleotide sequence of SEQ ID NO:15, classifiable in class 536, subclass 24.5, for example.
- V. Claims 5, 9, 14, 16, 18, and 20, drawn to a cell growth-suppressing agent, comprising a dsRNA, wherein the dsRNA comprises an RNA

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complementary to WT1 gene transcript, wherein the dsRNA comprises an RNA encoded by the DNA of any one of (a) to (c), and an RNA complementary to said RNA: (a) a DNA comprising the nucleotide sequence of SEQ ID NO:16; (b) a DNA that hybridizes under stringent conditions with a DNA comprising the nucleotide sequence of SEQ ID NO:16; and (c) a DNA comprising the nucleotide sequence of SEQ ID NO:17, classifiable in class 536, subclass 24.5, for example.

Claims 1, 6-8, 10-13, 15, 17, and 19 links the inventions of Groups I-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1, 2, 6-8, 10-13, 15, 17, and 19. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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The inventions are distinct, each from the other, because of the following reasons:

Groups I-V are directed to related inventions in that they all comprise a cell growth-suppressing agent, comprising a dsRNA, wherein the dsRNA comprises an RNA complementary to WT1 gene transcript. However, the related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions of Groups I-V are patentably distinct from each other since they are directed to mutually exclusive and distinct cell growth-suppressing agents, which are targeted to and complementary to different positions within the WT1 gene. Furthermore, the cell growth-suppressing agents are known in the art to possess materially different designs (e.g. nucleic acid sequences). For explanation, see pages 8 and 9 and Table 1. In this regard, a search of the cell growth-suppressing agent, comprising a dsRNA, wherein the dsRNA comprises an RNA complementary to a 17AA site of a WT1 gene transcript, and wherein the dsRNA comprises the pair of the nucleotide sequence of SEQ ID NO:1, and the nucleotide sequence of SEQ ID NO:2 of Group I would not necessarily reveal art against the cell growth-suppressing agents comprising different sequences with different SEQ ID NOs. of Groups II-V. Similarly, a search of cell growth-suppressing agents comprising different sequences with different SEQ ID NOs. of Group II would not necessarily reveal art against the cell growth-suppressing agents comprising different

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sequences with different SEQ ID NOs. of Groups III-V. Similarly, a search of the cell growth-suppressing agents comprising different sequences with different SEQ ID NOs. of Group III would not necessarily reveal art against the cell growth-suppressing agents comprising different sequences with different SEQ ID NOs. of Groups IV and V. Similarly, a search of the cell growth-suppressing agents comprising different sequences with different SEQ ID NOs. of Group IV would not necessarily reveal art against the cell growth-suppressing agents comprising different sequences with different SEQ ID NOs. of Group V. Because these groups utilize unique structures, namely, distinct cell growth-suppressing agents, targeted to and complementary to different regions within a WT1 gene transcript, with different nucleotide sequences, the inventions are therefore not obvious variants. Since it is a burden to search and examine these multiple inventions in a single application, due to the fact that the searches are divergent and non-coextensive, restriction is proper therefore.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To

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reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a


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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 10, 2008
/Terra Cotta Gibbs/

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| <i>Application Number</i>  | Application/Control No. | Applicant(s)/Patent under Reexamination | |
| | 10/594,939 | SUGIYAMA ET AL. | |
| | Examiner | Art Unit | |
| | TERRA C. GIBBS | 1635 | |
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